The following corrections or additions to the January 15, 1997 list were made in May, 1997

New Approvals

ANADA Number: 200-221

Pioneer Product:	140-897
Trade Name :	Component ™ TE-S
Ingredients:	Trenbolone acetate and estradiol
Sponsor:	Ivy Laboratories, Inc.
Approval Date:	03/20/97
Status:	Over-the-counter
Route:	Subcutaneous (ear)
Species:	Bovine
Drug Form:	Implant
Concentration:	120 mg trenbolone acetate and 24 mg estradiol/implant
Indications:	For increased rate of weight gain and improved feed efficiency in feedlot steers.
Tolerance:	Estradiol: 21CFR 556.240: the increments of estradiol permitted above the concentrations of estradiol naturally present in untreated animals are the following: 120 ppt in muscle, 240 ppt in liver, 360 ppt in kidney, and 480 ppt in fat. Trenbolone: 21CFR 556.739: the safe concentration for total trenbolone residues in uncooked edible tissues of cattle is 50 ppb in muscle, 100 ppb in liver, 150 ppb in kidney, and 200 ppb in fat.
Withdrawal:	Zero days.

21CFR 522.2477

ANADA Number: 200-174

Pioneer Product:	130-464
Trade Name :	Gentamicin Sulfate Pig Pump Oral Solution
Ingredients:	Gentamicin sulfate, USP
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	04/10/97
Status:	Over-the-counter
Route:	Oral
Species:	Porcine (neonatal)
Drug Form:	Liquid (solution)
Concentration:	5 mg/mL
Indications:	For treatment of colibacillosis in neonatal pigs 1-3 days of age.
Tolerance:	21CFR 556.300: 0.1 ppm in muscle, 0.3 ppm in liver, and 0.4 ppm in fat and kidney.
Withdrawal:	14 days.

21CFR 520.1044b

ANADA Number: 200-185

Pioneer Product: 133-836
Trade Name : Gen-Gard™ Soluble Powder
Ingredients: Gentamicin sulfate
Sponsor: Agri Laboratories, Ltd.
Approval Date: 04/30/97
Status: Over-the-counter
Route: Oral
Species: Porcine
Drug Form: Powder
Concentration: 333.33 mg gentamicin base/g gentamicin sulfate
Indications: For the control and treatment of colibacillosis in weanling swine caused by strains of *Escherichia coli* sensitive to gentamicin, and for the control and treatment of swine dysentery associated with *Treponema hyodysenteriae*.
Tolerance: 21CFR 556.300: 0.1 ppm in muscle, 0.3 ppm in liver, and 0.4 ppm in kidney and fat.
Withdrawal: 10 days.

21CFR 520.1044c

ANADA Number: 200-224

Pioneer Product: 138-612
Trade Name : Component™ T-S & Component™ T-H
Ingredients: Trenbolone acetate
Sponsor: Ivy Laboratories, Inc.
Approval Date: 04/30/97
Status: Over-the-counter
Route: Subcutaneous (ear)
Species: Bovine
Drug Form: Implant
Concentration: Component™ T-S: 140 mg/implant; Component™ T-H: 200 mg/implant.
Indications: For improved feed efficiency in growing-finishing feedlot steers (Component™ T-S); for increased rate of weight gain and improved feed efficiency in growing-finishing feedlot heifers (Component™ T-H).
Tolerance: 21CFR 556.739: The safe concentrations for total trenbolone residue in uncooked edible tissues of cattle are 50 ppb in muscle, 100 ppb in liver, 150 ppb in kidney, and 200 ppb in fat.
Withdrawal: Zero days.

21CFR 522.2476

ANADA Number: 200-200

Pioneer Product: 014-170
Trade Name : Halothane, USP
Ingredients: Halothane, USP
Sponsor: Halocarbon Laboratories
Approval Date: 04/10/97
Status: Prescription only
Route: Inhalation
Species: Canine, feline and other non-food animals
Drug Form: Liquid

Concentration: 99.9%
Indications: For induction and maintenance of general anesthesia.

21CFR 529.1115

NADA Number: 141-084

Trade Name : Sentinel™
Ingredients: Milbemycin oxime/lufenuron
Sponsor: Novartis Animal Health US, Inc.
Approval Date: 04/10/97
Status: Prescription only
Route: Oral
Species: Canine
Drug Form: Tablet
Concentration: 2.3 mg milbemycin oxime and 46 mg lufenuron/tablet
5.75 mg milbemycin oxime and 115 mg lufenuron/tablet
11.5 mg milbemycin oxime and 230 mg lufenuron/tablet
23.0 mg milbemycin oxime and 460 mg lufenuron/tablet
Indications: For the prevention of heartworm disease caused by *Dirofilaria immitis*, the control of adult *Ancylostoma caninum,* the removal and control of adult *Toxocara canis*, *Toxascaris leonina* and *Trichuris vulpis* infections, and the prevention and control of flea populations.
Exclusivity: 3 years

21CFR 520.1446

NADA Number: 141-081

Trade Name : ORBAX™
Ingredients: Orbifloxacin
Sponsor: Schering-Plough Animal Health Corporation
Approval Date: 04/22/97
Status: Prescription only
Route: Oral
Species: Canine
Drug Form: Tablet
Concentration: 5.7 mg, 22.7 mg, and 68 mg /tablet
Indications: For the management of diseases in dogs associated with bacteria susceptible to orbifloxacin.
Patent Number: 4,795,751 Expiration date: 10/28/2006
Exclusivity: 5 years

21CFR 520.1616

Supplemental Approvals

NADA Number: 140-940

Trade Name :	AVIAX® Premix for Broiler Chickens
Ingredients:	Semduramicin sodium
Sponsor:	Pfizer, Inc.
Approval Date:	04/08/97
Status:	Over-the-counter
Route:	Oral
Species:	Avian (chickens)
Drug Form:	Type A medicated article to make a Type C medicated feed.
Concentration:	Type A medicated article: 15.3% of semduramicin sodium.
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E.acervulina, E.maxima, E.brunetti, E.necatrix,* and *E.mivati/E.mitis*.
Tolerance:	The safe concentration for semduramicin in chicken muscle tissue is established at 360 ppb.

This supplemental application provides for a change in the assay limits from 85-110% to 80-110% for the Type C medicated feed.

21CFR 558.4

NADA Number: 113-232

Trade Name :	Liquamycin® LA-200®
Ingredients:	Oxytetracycline amphoteric
Sponsor:	Pfizer, Inc.
Approval Date:	04/23/97
Status:	Over-the-counter
Route:	Intramuscular, subcutaneous, or intravenous
Species:	Bovine (beef cattle, nonlactating dairy cattle, and calves including pre-ruminating (veal) calves), porcine
Drug Form:	Liquid (suspension)
Concentration:	200 mg/mL
Indications:	Bovine: for the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp.; bovine keratoconjunctivitis caused by *Moraxella bovis*; foot-rot and diphtheria caused by *Fusobacterium necrophorum*; bacterial enteritis (scours) caused by *Escherichia coli*; wooden tongue caused by *Actinobacillus lignieresii*; leptospirosis caused by *Leptospira pomona*; and wound infections and acute metritis caused by strains of staphylococci and streptococci organisms sensitive to oxytetracycline. Porcine: for the treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli*; pneumonia caused by *Pasteurella multocida*; and leptospirosis caused by *Leptospira pomona*. In sows, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*
Exclusivity:	3 years
Tolerance:	21CFR 556.500: 2 ppm in muscle, 6 ppm in liver, and 12 ppm in kidney and fat.
Withdrawal:	28 days.

This supplemental application provides for changes to the product labeling to include a subcutaneous route of administration in cattle. Also, the indications section of the labeling will be revised to include pre-ruminating (veal) calves.

21CFR 522.1660

NADA Number: 096-298

Trade Name :	Bovatec
Ingredients:	Lasalocid
Sponsor:	Hoffmann-La Roche, Inc.
Approval Date:	05/27/97
Status:	Over-the-counter
Route:	Oral
Species:	Bovine (pasture cattle: slaughter, stocker, feeder cattle, and dairy and beef replacement heifers).
Drug Form:	Type A medicated article used to make a Type C medicated liquid feed.
Concentration:	150 g/ton in the Type C liquid feed supplement.
Indications:	For increased rate of weight gain in pasture cattle.

This supplemental application provides for a technical correction of the International Feed Number (IFN) for the Condensed Molasses Fermentation Solubles as codified in 21 CFR 558.311(e)(3)(i). The IFN is to be removed and replaced by "N/A".

21CFR 558.311

NADA Number: 135-321

Trade Name :	BIO-COX®
	BMD®
	3-NITRO®
Ingredients:	Salinomycin sodium
	Bacitracin methylene disalicylate
	Roxarsone
Sponsor:	Hoffmann-La Roche, Inc.
Approval Date:	05/29/97
Status:	Over-the-counter
Route:	Oral
Species:	Avian (broiler chickens)
Drug Form:	Type A medicated articles
Concentration:	Salinomycin: 30 g of activity/lb of Type A medicated article.
	BMD: 30, 50, 60, and 75g of activity/lb Type A medicated article.
	Roxarsone: 45.4, 90, and 227 g of activity/lb Type A medicated article.
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E.necatrix, E.acervulina, E.maxima, E.brunetti,* and *E.mivati*, including some field strains of *E. tenella* that are more susceptible to roxarsone combined with salinomycin than to salinomycin alone; and for increased rate of weight gain in broiler chickens.
Exclusivity:	3 years
Tolerance:	BMD: 21CFR 556.70: 0.5 ppm negligible residue in uncooked edible tissues of chickens.
Withdrawal:	5 days

This supplemental application provides for the combined use of three approved Type A medicated articles (salinomycin, bacitracin methylene disalicylate, and roxarsone) in the manufacture of Type C medicated feeds, rather than a premix incorporating all of these compounds.

21CFR 558.550

Change of Sponsor

NADA Number: 031-971

From Schering-Plough Animal Health Corp. to:
Walco International, Inc.
Drug labeler code: 049185

NADA Number: 009-476; 098-378; 107-997; 108-115; 108-116

From Merck Research Laboratories, Division of Merck & Co., Inc. to:
Koffolk, Inc.
One Parker Plaza, Fort Lee, NJ 07024
Drug labeler code: 063271

Amendment of a Drug Labeler Code

The correct drug labeler code for ADM Animal Health & Nutrition Division is 017519.